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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
| 10/589,291 | 06/04/2007 | Tony N. Frudakis | DNA1180-2 | 7164 |
| 28213 | 7590 | 10/16/2008 | EXAMINER | |
| DLA PIPER LLP (US) 4365 EXECUTIVE DRIVE SUITE 1100 SAN DIEGO, CA 92121-2133 | | | GOLDBERG, JEANINE ANNE | |
| ART UNIT | PAPER NUMBER | | | |
| | 1634 | | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | |
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| Office Action Summary | Application No. 10/589,291 | Applicant(s) FRUDAKIS, TONY N. |
| | Examiner JEANINE A. GOLDBERG | Art Unit 1634 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(o).

Status

- 1) Responsive to communication(s) filed on 04 June 2007.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-28 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) _____ is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) 1-28 are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
 3) Information Disclosure Statement(s) (PTO/SB/08e)
 Paper No(s)/Mail Date _____
- 4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date. _____
- 5) Notice of Informal Patent Application
 6) Other: _____

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-13, drawn to a method for determining eye color.

Group II, claim(s) 14-20, drawn to an article.

Group III, claim(s) 21-24, drawn to a nucleic acid for eye color.

Group IV, claim(s) 24, drawn to a polypeptide for eye color.

Group V, claim(s) 24-27, drawn to a method for determining hair color.

Group VI, claim(s) 28, drawn to a nucleic acid composition.

Group VII, claim(s) 28, drawn to a composition of polypeptide.

Further Restriction Requirement

2. The claims are drawn to methods which require identifying at least one SNP in a nucleic acid sample to infer a phenotype. The claims are directed to numerous distinct methods recited in the alternative. The language "at least one SNP" requires that one, two, three or any number up to the recited SNP are detected within a target nucleic acid

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sample. For example, a method requiring SNP of SEQ ID NO: 1 is distinct from a method requiring SNP of SEQ ID NO: 2 because the methods have a different mode of operation, do not overlap in scope, and they are not obvious variants of one another (see MPEP 806.05(j)). As seen in the claims, each of the SNPs are located in distinct markers, genes and sequences and are related to different eye colors, for example. .

The claims further encompass many subcombinations which are disclosed as usable together in a single combination and which are also separately usable. For example, consider the following combinations of "one or more" SNP selected from those disclosed:

Subcombination (A): the method of inferring eye color using SNP within SEQ ID NO: 1 and 2

Subcombination (B): the method of inferring eye color using SNP within SEQ ID NO: 3 and 4

Combination (A+B): the method of inferring eye color using SNP within SEQ ID NO: 1, 2, 3, and 4.

Each of the combinations of SNPs are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct if they do not overlap in scope and are not obvious variants, and if it is shown that at least one subcombination is separately usable. In this case subcombinations (A) and (B) do not overlap in scope and there is no evidence on the record to suggest that they are

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obvious variants of one another. The subcombinations are separately usable as evidenced by their presentation in the alternative within the claims. Further, subcombination "A" has separate utility such as detecting the SNP, as a marker, or for linkage studies, for examples . So, subcombinations (A) and (B) are distinct. See MPEP § 806.05(d).

With respect to the SNPs claimed. Applicants are required to elect a single combination of SNPs for examination because the claims require "at least one" SNPs. The combination may be a single SNP or a combination of all SNPs. The polynucleotides would be regarded as having the same or corresponding technical feature if the alternatives had a common property or activity and shared a significant structural element that is essential to the common property or activity. The fact that all point mutations are within a defined sequence is not sufficient to establish unity of invention since the gene has already been described in the prior art and no functional relationship exists among the different SNPs claimed. Here, the claimed invention is drawn to the differences between a known gene and not the sequences the gene shares in common with other variants.

This example particularly discusses only the combinations (A), (B) and (A+B), but the same analysis could be applied to each of the different subcombinations and combinations set forth in the instant claims.

Applicant is required to select a single invention, ie, a single SNP or a single combination of SNPs required for the claimed method. The invention may be a single

SNP, a combination of more than one SNP but less than all of the disclosed SNP or a combination of all possible claimed SNPs. However, an election of a single invention, ie, a single SNP or a single combination of SNPs is required. This restriction requirement is predicated on the fact that the methods which use different SNPs or different combinations of SNPs do not appear obvious over one another. Should applicant traverse on the ground that the different SNPs or different combinations of SNPs are not patentably distinct over each other , applicant should submit evident or identify such evidence now of record showing the inventions to be obvious variant over each other or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other inventions.

Applicant is also required to identify which claims read upon the elected invention.

The examiner has required restriction between subcombinations usable together. Where applicant elects a subcombination and claims thereto are subsequently found allowable, any claim(s) depending from or otherwise requiring all the limitations of the allowable subcombination will be examined for patentability in accordance with 37 CFR 1.104. See MPEP § 821.04(a). Applicant is advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application.

Reasons

3. The groups of inventions listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Claim 24 is not a special technical feature that is a contribution over the art. Brennan (US Patent 5,474,796, December 12, 1995) teaches oligonucleotides having 10 nucleotides each (10-mers). The oligonucleotides represent every possible permutation of the 10-mer oligonucleotide. Brennan teaches a com position comprising a binding pair member that selectively binds to SEQ ID NO: 1-7.

Further Claim 14 is drawn to a picture of a person having a mutation. Prior to the filing of the application, pictures were taken of people having mutations. Whether the mutation was known to be part of the persons genetic make up, the picture would have existed.

With respect to the method claims requiring at least one SNP in the OCA2 gene, there is no special technical feature which is a contribution over the art. First, the art teaches the OCA2 gene (see Lee et al. Genomics, Vol. 26, pages 354-363, 1995).

Additionally, Frudakis et al. teaches SNPs within the OCA2 gene which are associated with iris colors (see Table 2). Thus, the OCA2 gene itself and mutations within the gene are not a contribution over the art and thus the claims lack a special technical feature.

Notice of Rejoinder

4. The examiner has required restriction between product and process claims.

Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

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In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

1. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jeanine Goldberg whose telephone number is (571) 272-0743. The examiner can normally be reached Monday-Friday from 7:00 a.m. to 4:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached on (571) 272-0735.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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The Central Fax Number for official correspondence is (571) 273-8300.

*/Jeanine Goldberg/
Primary Examiner
October 16, 2008*